

Appin No: 10/015,637
Filed: 17 December 2001
Office Action mailed 06 July 2004
Response faxed 06 October 2004

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Remarks

With this response, claims 2-4 and 14-15 are canceled. Claims 1, 5-13, and 17-24 are currently pending. Claims 1, 13, and 16 have been amended.

Further and favorable reconsideration of the subject application in light of the following remarks are respectfully requested.

Rejection under 35 U.S.C. § 112, Para. 1 Written Description

Claims 1-3, 5-15, and 17-24 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The Office Action states that applicants do not describe any polynucleotide promoter sequences that are 99%, 95%, or 94% identical to SEQ ID NO: 1. The Office Action further states that the specification fails to provide an adequate written description to support the genus of polynucleotides encompassed by the percent identity language as set forth in the claims.

The applicants respectfully disagree. It is well established that an applicant is not required to exemplify each and every claimed embodiment of his or her invention. Rather, "if a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then adequate written description requirement is met" (*In re Alton*, 37 USPQ2d 1578, 1584 (Fed. Cir.1996)).

Applicants have described the sequences for the full length form (SEQ ID NO: 14) and the deletion mutant forms (SEQ ID NOs: 1 and 2) of the Arc5 promoter. Applicants have also described multiple transformation vectors with both the full length and truncated sequences (page 39, Table 2). Given the detail of the description provided in the specification, applicants assert that one of skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing.

However, to facilitate prosecution, applicants have canceled claims 2-4 and 14-15, without prejudice. Additionally, claims 1 and 13 have been amended to omit the claim language "94% identical to" and to include the recitation of SEQ ID NO: 2. Support for the addition of

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SEQ ID NO: 2 is found in the original specification at Example 5 (page 42, line 12) and Figure 5. No new matter is introduced with these amendments.

Rejection under 35 U.S.C. § 112, Para. 1 Enablement

Claims 1-3 and 5-24 are rejected under U.S.C. §112, first paragraph, as allegedly not being enabled. The Office Action states that the specification is not enabled for the soybean plant cell where the sequence is at least 94%, 95%, or 99% identical to SEQ ID NO: 1. Additionally, the Office Action states that although the specification is enabling for soybean plant cells, the applicants give no guidance to any soybean plants. The Office Action cites the Tisserat reference to argue that the regeneration of plants from explants is unpredictable, and that explant selection is critical for successful plant regeneration. The Office Action asserts that undue trial and error experimentation would be required for one of ordinary skill in the art to screen through the multitude of non-exemplified sequences, in order to identify those polynucleotides, that when transformed into plant cells or plants, function as promoter sequences to produce the expression pattern and stoichiometry characteristics of SEQ ID NO: 1, in soybean cells and plants.

The applicants respectfully disagree. Applicants assert that it is well established that routine experimentation may be warranted to determine whether use of a thing or a method is or is not within the scope of a claim, and does not negate the patentability of the claim (*In re Wands*, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988)). Applicants have provided description for plant transformation procedures in the specification beginning at page 32 line 10, and beginning at page 41, line 20. Applicants have also provided description of regeneration of transformed plants from plant cells other than callus tissue, reaching much more than transgenic soybean cotyledons. Additionally, applicants have provided description of transformation vectors containing the promoters of the current invention driving the expression of GUS, the transformation of soybean plants with those vectors, and the confirmation of the expression of GUS in seeds and cotyledons of the resulting transformed soybean plants (Examples 4 and 5, and Figure 3). Applicants assert that the specification is enabled for transgenic soybean plants of the current invention.

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However, to facilitate prosecution, applicants have canceled claims 2-4 and 14-15, without prejudice. These canceled claims contained language to promoter sequences "at least 95% and 99% identical to SEQ ID NO: 1". Additionally, claims 1 and 13 have been amended to omit the claim language "94% identical to SEQ ID NO: 1" and to include the recitation of SEQ ID NO: 2. Support for the addition of SEQ ID NO: 2 is found in the original specification at Example 5 (page 42, line 12) and Figure 5. No new matter is introduced with these amendments.

Applicants respectfully submit that the 35 U.S.C. § 112, first paragraph rejections relating to enablement are unfounded and should be withdrawn.

Rejection under 35 U.S.C. § 103

Claims 1, 2, 3, 5-15, and 17-24 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Goosens *et al.* in view of Chee *et al.* The Office Action states that Goosens *et al.* teach a DNA sequence 99.7% identical to SEQ ID NO: 1. The Office Action further states that Goosens *et al.* teach a transformed *Phaseolus acutifolium* transgenic for an arcelin promoter and the Arc5 coding sequence where the promoter is heterologous to the structural gene.

Applicants respectfully disagree. Goosens *et al.* teach a genomic DNA sequence, but do not define the promoter, 3' UTR or 5' UTR regions. Goosens *et al.* do not teach a truncated promoter sequence of SEQ ID NO: 1 or 2 of the current application. Additionally, Goosens *et al.* suggest that the promoter, 5' UTR and 3' UTR are all needed for regulation. Goosens *et al.* state on page 1102, final paragraph, "The work presented here indicates that the 5' and 3' flanking sequences (1.1 and 0.6 kb, respectively) of the arc5-I seed storage protein gene contain most, if not all, of the essential information for correct developmental and spatial regulation and exceptionally high accumulation of the arcelin-5 protein in transgenic plants." Therefore, Goosens *et al.* do not teach the ability to use 5' UTR and 3' UTR sequences heterologous to the promoter sequence.

As a result, Goosens *et al.* when combined with the Chee *et al.* reference, do not render the present invention obvious.

Claim Objections

The Office Action has objected to claim 4 as being dependent upon a rejected claim. The Office Action further states that claim 4 would be allowable if rewritten in independent form

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including all the limitations of the base claim and intervening claims. Claim 4 has been canceled. Claim 1 has been amended to contain the limitations of claim 4, and to add SEQ ID NO: 2.

It is not believed that extensions of time or fees for net addition of claims are required beyond those that may otherwise be provided for in the documents accompanying this paper. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefore (including fees for net addition of claims) are hereby authorized to be charged to our Deposit Account Number 50-1100, referencing docket number REN-00-027-US. Applicants likewise authorize a charge to Deposit Account Number 50-1100 for any other fees related to the present application that are not otherwise provided for in the accompanying documents.

Should the Examiner have any questions regarding this application, the Examiner is encouraged to contact Applicants' undersigned representative at (847) 236-5101.

Respectfully submitted,



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